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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/070,656	04/09/2003	Gianfranco Merizzi	43531	9742

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EXAMINER
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FLOOD, MICHELE C

ART UNIT	PAPER NUMBER
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1654

DATE MAILED: 02/25/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

10/070,656

**Applicant(s)**

MERIZZI, GIANFRANCO

**Examiner**

Michele C. Flood

**Art Unit**

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 04 June 2002.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. §§ 119 and 120

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All   b) ☐ Some \*   c) ☐ None of:
- 1) ☐ Certified copies of the priority documents have been received.
  - 2) ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - 3) ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 0602.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding Claim 1, the phrase "which is particularly useful" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention.

The metes and bounds of Claim 1 are rendered uncertain by the phrase "useful in the prevention and treatment of circulation problems and in the treatment of adiposity" because it is unclear as to what subject the claimed composition is intended to provide the claimed functional effect. The lack of clarity renders the claim ambiguous.

Regarding Claim 1, line 5, the phrase "in association" renders the claim vague and indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention.

Claim 2 recites the limitation "the aforesaid active principles" in lines 2 to 3. There is insufficient antecedent basis for this limitation in the claim.

Claims 1-3 recite the phrase, "characterised in that it. Although the phrase does not raise to the level of indefiniteness and the word "characterised" is misspelled, it is

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suggested to replace the abovementioned phrase with wherein to provide clarity and consistency in the claim language.

The claims are generally narrative and indefinite, failing to conform with current U.S. practice. They appear to be a literal translation into English from a foreign document and are replete with grammatical and idiomatic errors.

All other cited claims depend directly or indirectly from rejected claims and are, therefore, also, rejected under U.S.C. 112, second paragraph for the reasons set forth above.

### ***Claim Objections***

Claims 4-11 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot depend from any other multiple dependent claim. See MPEP § 608.01(n). Accordingly, the claims have not been further treated on the merits.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Berdal (N) in view of Fukuda (A) and Kim et al. (B).

Applicant claims a composition based on plant extracts, with an antioxidant activity which is particularly useful in the prevention and treatment of circulation problems and in the prevention and treatment of adiposity, characterized in that its active ingredients comprise, in association, biflavones of *Ginkgo biloba*, catechine and/or derivatives thereof, iodine and a component chosen from among madecassic acid, asiatic acid, asiaticoside, and mixtures of these. Applicant further claims a composition according to Claim 1, wherein it is obtained by mixing plant extracts containing the aforesaid active principles. Applicant further claims a composition according to Claim 2, wherein the extracts are in phytosomal form.

Berdal teaches a composition comprising plant extracts of *Ginkgo biloba*, *Vitis vinifera*, and *Aescus hippocasteanum*, on page 6, lines 11-25. The composition taught by Berdal has vasculoprotective activity and at least one component with general and/or cerebral stimulant activity. Berdal further teaches that the plant extracts used in the making of the referenced composition comprise biologically active components, e.g., biflavones, heterosides an/or glucosides (of *Ginkgo biloba*), catechins, leucoanthocyanins, anthocyanoside, aesculoside, coumarine, etc.

The teachings of Berdal were set forth above. Berdal teaches the claimed composition except for iron and a component selected from the group consisting of madecassic acid, asiatic acid, asiaticoside, and mixtures thereof. However, it would have been obvious to one of ordinary skill in the art to add the instantly claimed

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ingredients to the composition taught by Berdal to provide the claimed composition because at the time the invention was made it was known in the art that the claimed ingredients were useful in the making of compositions which are used in the treatment of problematic circulatory disease conditions, as evidenced by the teachings of Fukuda and Kim. Firstly, Fukuda teaches a composition comprising a brown algae and iron. The composition taught by Fukuda is used as a dietary supplement for decreasing the sodium content in a living body, consequently decreasing the blood pressure of the living body. See Column 1, lines 7-15. Secondly, Kim teaches an extract of asiaticoside and madecassoside from *Centella asiatica*, which is effective in the protection and the anti-fibrosis of liver cells when administered to animals. In Column 1, lines 13-34, Kim further teaches, "[*Centella asiatica*] has been used for the treatment of a local wound since a long time ago"; and, "[extract of *Centella asiatica*, TECA] is acknowledged as a medicinal effector and commercially available under the tradename of "Madecassol" (asiaticoside: asiatic acid: madecassic acid 4:3:3)." At the time the invention was made, one of ordinary skill in the art would have been motivated and one would have had a reasonable expectation to add the ingredients taught by Fukuda and Kim to the composition taught by Berdal to provide the instantly claimed invention because Berdal taught that the referenced composition improves tissue hemodynamic conditions, increase cell nutrient assimilation capacity, and has cytoprotective effect; Fukuda teaches that iron-bonded algae extracts administered to animals adsorb sodium ions to suppress the absorption of sodium through the animals' digestive tract and prevents hypertension and cerebral apoplexy; and, Kim teaches that extracts of

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*Centella asiatica* comprising components of madecassic acid, asiatic acid, asiaticoside protect liver cells with an anti-fibrosis effect, and restore damaged tissue cells, and cures surgical wounds when administered to animals.

Moreover, it would have been obvious to one of ordinary skill in the art at the time the invention was made to add any of the claimed ingredients in the making of the claimed methods because it is well known that its *prima facie* obvious to combine two or more ingredients each of which is taught by the prior art to be useful for the same purpose in order to form a third composition which is useful for the same purpose. The idea for combining them flows logically from their having been used individually in the prior art. *In re Pinten*, 459 F. 2d 1053, 173 USPQ 801 (CCPA 1972); *In re Susi*, 58 CCPA 1074, 1079-80; 440 F.2d 442, 445; 169 USPQ 423, 426 (1971); *In re Crockett*, 47 CCPA 1018, 1020-21; 279 F.2d 274, 276-277; 126 USPQ 186, 188 (1960). Thus, at the time the invention was one of ordinary skill in the art would have been motivated and one would have had a reasonable expectation of success to add the claimed ingredients taught by Fukuda and Kim to the composition taught by Berdal to provide the claimed composition because the claimed composition is no more than the combining of well known ingredients used in well known methods for the treatment of circulatory disease conditions and for the treatment of adiposity.

Accordingly, the claimed invention was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michele C. Flood whose telephone number is (703) 308-9432. The examiner can normally be reached on 7:00 AM - 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on (703) 306-3220. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

*Michele C. Flood*  
**MICHELE FLOOD**  
**PATENT EXAMINER**  
MCF  
January 15, 2004